



Clinical Criteria for Hepatitis C (HCV) Therapy

Pre-Treatment Evaluation

- Must have chronic hepatitis C and HCV genotype and sub-genotype documented;
- Patients who have prior exposure to DAA therapy must have a pre-DAA genotype and post-DAA genotype documented (Appendix A);
- HCV RNA quantitative within 90 days of application for therapy;
- Liver biopsy or other accepted fibrosis test;
- Previous HCV treatment history and outcome;
- HIV status and, if HIV positive, current antiretroviral regimen and degree of viral suppression within 6 months of application for therapy;
- HBV status and, if active HBV disease, current antiretroviral regimen and degree of viral suppression within 6 months of application for therapy;
- Adherence evaluation: Providers must assess and document the patient's ability to adhere to therapy;
- Drug resistance testing as indicated; and

Patient Treatment Plan

- It is required that the patient have a treatment plan developed by, or in collaboration with, a provider with expertise in Hepatitis C management. [Sample treatment plan documents are available for use.](#)
- If the patient or their partner is of childbearing age, at least two (2) forms of contraception must be used (by the patient or their partner) if a RBV-containing regimen is prescribed throughout the duration of therapy and for six (6) months after the regimen is completed.

Drug Therapy

- Must be in accordance with FDA approved indications.

Treatment Options¹:

Genotype 1a:

- **Elbasvir/grazoprevir (Zepatier™)²**
 - Prior to requesting/initiating therapy with this agent, genotype testing for baseline NS5A polymorphisms is REQUIRED, in order to determine treatment length.

- Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required.

Patient characteristics	Treatment	Treatment length
Treatment naïve, without baseline NS5A polymorphisms	Zepatier	12 weeks
Treatment naïve, with baseline NS5A polymorphisms	Zepatier + weight based ribavirin	16 weeks
Treatment experienced (PegIFN/RBV), without baseline NS5A polymorphisms	Zepatier	12 weeks
Treatment experienced (PegIFN/RBV), with baseline NS5A polymorphisms	Zepatier + weight based ribavirin	16 weeks

○ Glecaprevir/pibrentasvir (Mavyret™)⁶

- Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required.

Patient characteristics	Treatment length
Treatment naïve, without cirrhosis	8 weeks
Treatment naïve, with compensated cirrhosis	8 weeks
Treatment experienced, without cirrhosis	8 weeks
Treatment experienced, with compensated cirrhosis	12 weeks

○ Ledipasvir/sofosbuvir (Harvoni®)³

Patient characteristics	Treatment length
Treatment naïve, without cirrhosis*	12 weeks
Treatment naïve, with cirrhosis	12 weeks
Treatment experienced, without cirrhosis	12 weeks
Treatment experienced, with cirrhosis**	24 weeks

*8 weeks of treatment can be considered in treatment naïve patients without cirrhosis who have pretreatment HCV RNA levels less than 6 million IU/mL.

**A 12 week regimen with weight-based ribavirin may be considered.

○ **Sofosbuvir/velpatasvir (Epclusa®)**⁴

Patient characteristics	Treatment	Treatment length
Patient without cirrhosis and with compensated cirrhosis (Child-Pugh A)	Epclusa	12 weeks
Patients with decompensated cirrhosis (Child-Pugh B and C)	Epclusa + weight based ribavirin	12 weeks

○ **Sofosbuvir/velpatasvir/voxilaprevir (Vosevi™)**⁵

- Prior DAA experience with an NS5A inhibitor or sofosbuvir
- Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required.

Genotype 1b:

○ **Elbasvir/grazoprevir (Zepatier™)**²

- Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required.

Patient characteristics	Treatment length
Treatment naïve	12 weeks
Treatment experienced (PegIFN/RBV)	12 weeks

○ **Glecaprevir/pibrentasvir (Mavyret™)**⁶

- Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required.

Patient characteristics	Treatment length
Treatment naïve, without cirrhosis	8 weeks
Treatment naïve, with compensated cirrhosis	8 weeks
Treatment experienced, without cirrhosis	8 weeks
Treatment experienced, with compensated cirrhosis	12 weeks

○ **Ledipasvir/sofosbuvir (Harvoni®)**³

Patient characteristics	Treatment length
Treatment naïve, without cirrhosis*	12 weeks
Treatment naïve, with cirrhosis	12 weeks
Treatment experienced, without cirrhosis	12 weeks
Treatment experienced, with cirrhosis**	24 weeks

*8 weeks of treatment can be considered in treatment naïve patients without cirrhosis who have pretreatment HCV RNA levels less than 6 million IU/mL.

**A 12 week regimen with weight-based ribavirin may be considered.

○ **Sofosbuvir/velpatasvir (Epclusa®)⁴**

Patient characteristics	Treatment	Treatment length
Patient without cirrhosis and with compensated cirrhosis (Child-Pugh A)	Epclusa	12 weeks
Patients with decompensated cirrhosis (Child-Pugh B and C)	Epclusa + weight based ribavirin	12 weeks

○ **Sofosbuvir/velpatasvir/voxilaprevir (Vosevi™)⁵**

- Prior DAA experience with an NS5A inhibitor
- Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required.

Genotype 2:

○ **Glecaprevir/pibrentasvir (Mavyret™)⁶**

- Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required.

Patient characteristics	Treatment length
Treatment naïve, without cirrhosis	8 weeks
Treatment naïve, with compensated cirrhosis	8 weeks
Treatment experienced, without cirrhosis	8 weeks
Treatment experienced, with compensated cirrhosis	12 weeks

○ **Sofosbuvir/velpatasvir (Epclusa®)⁴**

Patient characteristics	Treatment	Treatment length
Patient without cirrhosis and with compensated cirrhosis (Child-Pugh A)	Epclusa	12 weeks
Patients with decompensated cirrhosis (Child-Pugh B and C)	Epclusa + weight based ribavirin	12 weeks

- **Sofosbuvir/velpatasvir/voxilaprevir (Vosevi™)⁵**
 - Prior DAA experience with an NS5A inhibitor
 - Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required.

Genotype 3:

- **Glecaprevir/pibrentasvir (Mavyret™)⁶**
 - Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required.

Patient characteristics	Treatment length
Treatment naïve, without cirrhosis	8 weeks
Treatment naïve, with compensated cirrhosis	8 weeks
Treatment experienced, without cirrhosis	16 weeks
Treatment experienced, with compensated cirrhosis	16 weeks

- **Sofosbuvir/velpatasvir (Epclusa®)⁴**

Patient characteristics	Treatment	Treatment length
Patient without cirrhosis and with compensated cirrhosis (Child-Pugh A)	Epclusa	12 weeks
Patients with decompensated cirrhosis (Child-Pugh B and C)	Epclusa + weight based ribavirin	12 weeks

- **Sofosbuvir/velpatasvir/voxilaprevir (Vosevi™)⁵**
 - Prior DAA experience with an NS5A inhibitor or sofosbuvir
 - Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required.

Genotype 4:

- **Elbasvir/grazoprevir (Zepatier™)²**
 - Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required.

Patient characteristics	Treatment	Treatment length
Treatment naïve	Zepatier	12 weeks
Treatment experienced (PegIFN/RBV)	Zepatier + weight based ribavirin	16 weeks

○ **Glecaprevir/pibrentasvir (Mavyret™)⁶**

- Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required.

Patient characteristics	Treatment length
Treatment naïve, without cirrhosis	8 weeks
Treatment naïve, with compensated cirrhosis	8 weeks
Treatment experienced, without cirrhosis	8 weeks
Treatment experienced, with compensated cirrhosis	12 weeks

○ **Ledipasvir/sofosbuvir (Harvoni®)³**

Patient characteristics	Treatment length
Treatment naïve, with or without cirrhosis	12 weeks
Treatment experienced, with or without cirrhosis	12 weeks

○ **Sofosbuvir/velpatasvir (Epclusa®)⁴**

Patient characteristics	Treatment	Treatment length
Patient without cirrhosis and with compensated cirrhosis (Child-Pugh A)	Epclusa	12 weeks
Patients with decompensated cirrhosis (Child-Pugh B and C)	Epclusa + weight based ribavirin	12 weeks

○ **Sofosbuvir/velpatasvir/voxilaprevir (Vosevi™)⁵**

- Prior DAA experience with an NS5A inhibitor
- Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required.

Genotype 5 and 6:

○ **Glecaprevir/pibrentasvir (Mavyret™)⁶**

- Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required.

Patient characteristics	Treatment length
Treatment naïve, without cirrhosis	8 weeks
Treatment naïve, with compensated cirrhosis	8 weeks
Treatment experienced, without cirrhosis	8 weeks
Treatment experienced, with compensated cirrhosis	12 weeks

○ **Ledipasvir/sofosbuvir (Harvoni®)³**

Patient characteristics	Treatment length
Treatment naïve, with or without cirrhosis	12 weeks
Treatment experienced, with or without cirrhosis	12 weeks

○ **Sofosbuvir/velpatasvir (Epclusa®)⁴**

Patient characteristics	Treatment	Treatment length
Patient without cirrhosis and with compensated cirrhosis (Child-Pugh A)	Epclusa	12 weeks
Patients with decompensated cirrhosis (Child-Pugh B and C)	Epclusa + weight based ribavirin	12 weeks

○ **Sofosbuvir/velpatasvir/voxilaprevir (Vosevi™)⁵**

- Prior DAA experience with an NS5A inhibitor
- Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required.

References:

1. AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. <http://www.hcvguidelines.org>. March 13, 2019 accessed.
2. Zepatier [package insert]. Whitehouse Station, NJ: Merck and Co., Inc., January 2016.
3. Harvoni [package insert]. Foster City, CA: Gilead Sciences, Inc., November 2019.
4. Epclusa [package insert]. Foster City, CA: Gilead Sciences, Inc., November 2019.
5. Vosevi [package insert]. Foster City, CA: Gilead Sciences, Inc., November 2019.
6. Mavyret [package insert]. North Chicago, IL: AbbVie Inc., September 2019.

Appendix A: HCV Treatment Definitions

Retreatment: Previous exposure to an HCV treatment direct acting antiviral (DAA) regimen, which does NOT result in achievement of SVR and current need for an additional course of therapy to treat chronic HCV infection.

Conditions required:

- Detectable HCV RNA at 12 weeks post treatment.
- HCV genotype is the SAME before and after the INITIAL HCV treatment regimen.

Reinfection: Exposure to an HCV treatment regimen, which results in achievement of SVR.

Conditions required:

- Detectable HCV RNA > 12 weeks post treatment
- HCV genotype is DIFFERENT after the INITIAL HCV treatment regimen.
- Current infection has been present ≥ 6 months.